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QM32/0316

ART UNIT JAWORSKI, F	PAPER NUMBER 2
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3727
DATE MAILED:

03/16/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 3-19-99
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-5 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-5 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892 1 sheet
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

09/272,764

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

Art Unit: 3737

1. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1 the claim recites the intended or desired results as opposed to the method steps of 'applying...', 'measuring...', and the ultrasound system is recited as structure as opposed to a step of 'transmitting....with an ultrasound system...(and).....receiving...'.

Additionally the terms sub(ultra)harmonic are vague in context since the transmit portion has not been established to operate at a fundamental frequency so as to define any harmonics. This issue carries forward throughout the claims.

With respect to claim 2, the fundamental frequency issue applies. Additionally the claim is incomplete since the preamble recites measurement of pressure change whereas the body of the claim infers a pressure estimation. Additionally it is unclear how the 'at least one..transducer' relates to the transmitting/receiving since every ultrasound system needs same to have basic function.

With respect to claim 3, the claim is incomplete for purposes of the preamble since no structure for pressure change measurement is recited.

With respect to claim 4, it is unclear from the language 'containing' whether an open (comprising) or closed (consisting of) construct is intended. Additionally it is not completely clear that the microbubbles are adapted for physiologic measurement as opposed to industrial use since the stipulation that the bubbles have size uniformity if placed in a mammalian bloodstream does

Art Unit: 3737

not appear to exclude usage elsewhere under one interpretation whereas under another equally reasonable it does exclude in vitro usage be it hemodialysis or bloodbag or cardiopulmonary bypass or industrial pipe testing.

With respect to claim 5, the 'applying/measuring' issue regarding claim 1 applies. Additionally the 'application' step is vague insofar as the preamble is specific to the estimation of pressure change within a mammal. For example would the external application of a microbubble solution to chamber of a manometric pressure line extending from the patient and equilibrated via a diaphragm be embraced by the claim? Additionally it is unclear whether the measurement step is carried out using the ultrasound system since it is stated only to be involved with signal receipt.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 2-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Miwa (US4483345). Miwa teaches use of a native cavitation phenomenon wherein microbubbles are generated by low frequency 10khz sweep across their resonance as per Fig. 1 and col. 1 lines 57-63, and the critical cavitation pressure P_c may, with known ambient pressure P_a serve in the col. 4 line 40 equation to determine arterial pulse pressure at the measurement time $P_p(t_c)$. Referring to Fig. 7, this scheme is incorporated into a measurement system and method wherein 1 is the sweep

Art Unit: 3737

resonator inducing cavitation for the microbubble formation which is detected by array 5 in conjunction with doppler bandpass filtering to extract high or low frequency harmonics (Abstract and col. 10 lines 5-16). The Col. 7 lines 40-44 array teaching wrt element 5 suffices to additionally reject claim 3.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2, 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tickner (US4265251) in view of Sliwa, Jr. et al (US5749364). Tickner in Fig. 4 is directed to a non-imaging single-transducer ultrasound system using an injectate of uniform size microbubbles as per col. 3 lines 6-33 with analog filtering 42 so as to provide an output proportional to resonance frequency and therefore to pressure. It would have been obvious in view of Sliwa, Jr. et al as per col. 2 lines 11-35 to utilize sub or super-harmonics to perform the pressure measurement in Tickner since this puts the returned signals outside the range of the fundamental interrogating pulse for the measurement.

6. With respect to composition claim 4, this claim is met by the cited passages in Tickner and Sliwa, Jr. et al and the inherent property of compressibility of gases within a fluid. Alternately stated, Tickner poses a compositional solution which provides small uniform sized bubbles with left-to-right cardiovascular passage stability. Bubble compressibility is inherent since they are

Art Unit: 3737

gas-filled and exist within a liquid and resonate. This resonance is a natural phenomenon centered upon the harmonics such that Sliwa Jr. et al merely calls this to light.

7. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tickner in view of Sliwa Jr. et al as applied to claims above, and further in view of Schlieff et al (US5195520), insofar as the latter teaches that both amplitude and frequency changes may be evaluated in order to ascertain pressure in the medium under test using microbubble scatterers.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tickner in view of Sliwa, Jr. et al as applied to claims above, and further in view of Miwa as per col. 7 lines 40-44 since the attendant advantage of an array to provide directionality to ribcage interrogation of the heart (In Fig. 7 element 5 cooperates in positional registry with secondary scanner 50 to provide directionality as specified by line cursor on display 56) would be useful for Tickner to interrogate the heart from a confined intercostal space pulse emission point..


9. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Sliwa, Jr. et al, insofar as array 26 is used to ensonate contrast agents for harmonic effects col. 1 line 37 - col. 2 line 59 with measurement of amplitude and/or resonant frequency changes col. 5 lines 63-67 and col. 6 line 45 - col. 7 line 23.

10. Wheatley (US5352436) is cited for its uniform bubble population size teaching Fig. 1 and the proportional graph for contrast agent echo amplitude versus dosage Fig. 2.

11. Katakura et al(US5535747) and Horton (US3640271) are less relevant teachings of the use of microbubbles in physiologic pressure measurements.

Art Unit: 3737

12. Any inquiry concerning this communication should be directed to Examiner Francis J. Jaworski at telephone number (703) 308-3061.



Francis J. Jaworski
Primary Examiner

FJJ:fjj

1-24-00